

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	09/937066
Filing Date	September 20, 2001
First Named Inventor	ALPAR, Hazire
Art Unit	1643
Examiner Name	Hines, JaNa A.

Sheet	1	of	4	Attorney Docket No: 41577-263691
-------	---	----	---	----------------------------------

## US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number Number-Kind Code	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,126,147	06-30-1992	Silvestri, et al.	
		US-5,585,106	12-17-96	Gristina, et al.	
		US-5,643,605	07-01-1997	Cleland, et al.	
		US-5,942,252	08-24-1999	Tice, et al.	
		US-6,098,619	08-2000	Britto, et al.	
		US-6,309,623	10-31-2001	Weers, et al.	
		US-6,428,771	08-06-2002	Steiner, et al.	
		US-2002/0103165	08-01-2002	Bot, et al.	
		US-2005/0181063	08-18-2005	Alpar, et al.	
		US-2006/0239931	10-26-2006	Eyles, et al.	
		US-2008/0131377	06-05-2008	Eyles, et al.	
		US-2008/0057083A1	06-03-2008	Alpar, et al.	
		US-5,985,285	11-16-1999	Titball, et al.	
		US-2003/0171258A1	09-11-2003	Alpar et al.	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document Country Code Number Kind Code	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*
		WO 92/17165	10-15-1992	CSL Limited		
		WO 94/15636	07-21-1994	CSL Limited		
		WO 96/28551	09-19-1996	The Secretary of State for Defence		
		WO 98/33487	08-06-1998	Chiron Corp.		
		WO 00/56282	09-28-2000	The Secretary of State for Defence		
		WO 00/56361	09-28-2000	The Secretary of State for Defence		
		WO 02/43705	06-06-2002	Univ. of Florida		
		EP0571671	12-01-1993	The Procter and Gamble Company		

## OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T*
		ALONSO, M., et al., "Biodegradable Microspheres as Controlled-Release Tetanus Toxoid Delivery Systems," <i>Vaccine</i> , 1994 Vol. 12 No. 4, pp. 299-306.	

EXAMINER

DATE CONSIDERED

\* EXAMINER: Initial if reference considered, whether or not citation is in conformity with MPEP 809. Draw line through citation if not in conformity and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	09/937066
<b>Filing Date</b>	September 20, 2001
<b>First Named Inventor</b>	ALPAR, Hazire
<b>Art Unit</b>	1643
<b>Examiner Name</b>	Hines, JaNa A.

Sheet 2 of 4

Attorney Docket No: 41577-263691

	BECK, <i>et al.</i> , "A New Long-Acting Injectable Microcapsule System for the Administration of Progesterone," <i>Fertility and Sterility</i> , 1979, Vol. 31, pp. 545-551.	
	BRANDTZAEG, P., "Immune Functions of Human Nasal Mucosa and Tonsils in Health and Disease," <i>Immunology of the Lung and Upper Respiratory Tract</i> , (ed. Bienenstock J.). McGraw-Hill, New York, 1984, pp. 28-95.	
	ELVIN, S.J., <i>et al.</i> , "Protection against Bubonic and Pneumonic Plague with a Single Dose Microencapsulated Sub-Unit Vaccine," 2006, Vol. 24, pp. 4433-4439	
	EYLES, J., <i>et al.</i> , "Immune Responses to Mucosally Administered Co-encapsulated <i>Yersinia Pestis</i> Antigens," <i>J. Pharm. Pharmacol.</i> , 1997 Vol. 49, Suppl. 4, p. 85.	
	EYLES, J., <i>et al.</i> , "Generation of Protective Immune Responses to Plague by Mucosal Administration of Microsphere Co-encapsulated Recombinant Subunits," <i>Journal of Controlled Release</i> , 2000, Vol. 63 pp. 191-200.	
	EYLES, J., <i>et al.</i> , "Protection from Pneumonic Plague Following Intra-Nasal Immunisation with Microencapsulated <i>Y. Pestis</i> Antigens: A Dose Response Study," <i>Vaccines</i> , 2-5 December 1997, 14.23.	
	EYLES, <i>et al.</i> , "Protection studies following bronchopulmonary and intramuscular immunization with <i>Yersinia pestis</i> F1 and V subunit vaccines coencapsulated in biodegradable microspheres: a comparison of efficacy," <i>Vaccine</i> , 2000, Vol. 18, pp. 3266-3271.	
	EYLES, <i>et al.</i> , "Analysis of local and systemic immunological responses after intra-tracheal, intra-nasal and intra-muscular administration of microsphere co-encapsulated <i>Yersinia pestis</i> sub-unit vaccines," <i>Vaccine</i> , 1998, Vol. 16, No. 20, pp. 2000-2009.	
	EYLES, <i>et al.</i> , "Microspheres translocation and immunopotentiality in systemic tissues following intranasal administration," <i>Vaccine</i> , 2001, Vol. 19, pp. 4732-4742.	
	ELDRIDGE, J., <i>et al.</i> , "New Advances in Vaccine Delivery Systems," <i>Seminars in Hematology</i> , 1993, Vol. 30, No. 4, Suppl. 4 (October), pp 16-25.	
	FLICK-SMITH, H. C., <i>et al.</i> , "Mucosal or Parenteral Administration of Microsphere-Associated Bacillus anthracis Protective Antigen Protects against Anthrax Infection in Mice," 2002, Vol. 70, pp. 2022-2028	
	HILBERT, A., <i>et al.</i> , "Biodegradable Microspheres Containing Influenza A Vaccine: Immune Response in Mice," <i>Vaccine</i> , 1999, Vol. 17, pp. 1065-1073.	
	JENKINS, P., <i>et al.</i> , "Aspects of the Design and Delivery of Microparticles for Vaccine Applications," <i>Journal of Drug Targeting</i> , 1995, Vol. 3, pp. 79-81.	
	LEARY, E., <i>et al.</i> , "Active Immunization with Recombinant V Antigen From <i>Yersinia pestis</i> Protects Mice Against Plague," <i>Infection and Immunity</i> , 1995, Vol. 63, No. 8, pp. 2854-2858.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional) Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***Complete if Known*

<b>Application Number</b>	09/937066
<b>Filing Date</b>	September 20, 2001
<b>First Named Inventor</b>	ALPAR, Hazire
<b>Art Unit</b>	1643
<b>Examiner Name</b>	Hines, JaNa A.

(Use as many sheets as necessary)

Sheet

3

of

4

Attorney Docket No: 41577-263691

	LOWELL, G. H., et al., "Intranasal and Intramuscular Proteosome-Staphylococcal Enterotoxin B (SEB) Toxoid Vaccines: Immunogenicity and Efficacy against Lethal SEB Intoxication in Mice," <i>Infection and Immunity</i> , 1996, Vol. 64, pp. 1706-1713	
	MORRIS, W., et al., "Potential of Polymer Microencapsulation Technology for Vaccine Innovation," <i>Vaccine</i> , 1994, Vol. 12, No. 1, pp. 5-11.	
	OGAWA, Y., et al., "A New Technique to Efficiently Entrap Leuprolide Acetate into Microcapsules of Polylactic Acid or Copoly (Lactic/Glycolic) Acid," <i>Chem. Pharm. Bull.</i> , 1988, Vol. 36 No. 3, pp. 1095-1103.	
	O'HAGAN, D., et al., "Microparticles as Potentially Orally Active Immunological Adjuvants," <i>Vaccines</i> , 1989, Vol. 7, pp. 421-424.	
	PURDY, et al., "Pasteurella haemolytica Ultraviolet-Irradiated Vaccine by Parenteral and Aerosol Routes Compared in the Goat Model," <i>Current Microbiology</i> , 1998, Vol. 37, pp. 132-136.	
	RUSSELL, P., "A comparison of Plague vaccine, USP and EV76 vaccine induced protection against <i>Yersinia pestis</i> in a murine model," <i>Vaccine</i> 1995, Vol. 13, No. 16, pp. 1551-1556	
	TABATA, Y. AND IKADA, Y., "Phagocytosis of Polymer Microspheres by Macrophages," <i>Advances in Polymer Science</i> , 1990, Vol. 94, 107-141.	
	VAN ROOIJEN, N., "Antigen Processing and Presentation in Vivo: the Microenvironment as a Crucial Factor," <i>Immunology Today</i> , 1990, Vol. 11, No. 12, pp. 436-439.	
	VIDARD, L., et al., "Analysis of MHC Class II Presentation of Particulate Antigens by B Lymphocytes," <i>Journal of Immunology</i> , 1996, Vol. 156, pp. 2809-2818.	
	WALKER, R., "New Strategies for Using Mucosal Vaccination to Achieve More Effective Immunization," <i>Vaccine</i> , 1994, Vol. 12, No. 5, pp. 387-400.	
	WILLIAMSON, E., et al., "Local and Systemic Immune Response to a Microencapsulated Sub-Unit Vaccine for Plague," <i>Vaccine</i> , 1996, Vol. 14, No. 17/18, pp. 1613-1619.	
	WILLIAMSON, E, et al., "A sub-unit vaccine elicits IgG in serum, spleen cell cultures and bronchial washings and protects immunized animals against pneumonic plague," <i>Vaccine</i> , 1997, Vol. 15, No. 10, pp. 1079-1084	
	YAN, C., et al., "Intranasal Stimulation of Long-lasting Immunity Against Aerosol Ricin Challenge with Ricin Toxoid Vaccine Encapsulated in Polymeric Microspheres," <i>Vaccine</i> , 1996, Vol. 14, No. 11, pp. 1031-1038.	
	ZENG, M.Z., et al., "The Controlled Delivery of Drugs to the Lung," <i>International Journal of Pharmaceutics</i> , 1995, Vol. 124, pp. 149-164	
	Unpublished U.S. Patent Application Serial No. 09/937,065, filed 09-20-2001	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

*Complete if Known*

<b>Application Number</b>	09/937066
<b>Filing Date</b>	September 20, 2001
<b>First Named Inventor</b>	ALPAR, Hazire
<b>Art Unit</b>	1643
<b>Examiner Name</b>	Hines, JaNa A.

Sheet

4

of

4

Attorney Docket No: 41577-263691

Unpublished U.S. Patent Application Serial No. 09/937,068, filed 09-20-1991

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.